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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/709,477

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT

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1617

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/709,477	Applicant(s) PREUILH ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,37-42,44,46 and 52-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,37-42,44,46 and 52-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/26/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2007, has been entered.

Claims 31-32, 37-42, 44, 46 and 52-67 are pending in the application and are being examined on the merits herein.

The rejection of claim 67 under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Hirota, The Handbook of Cosmetic Science and Technology, Kligman, Cauwet et al. and Mueller et al, is being withdrawn in view of Applicants' arguments and remarks. In particular, Applicants have demonstrated in the declaration filed under 37 C.F.R. 1.132 on February 26, 2007 and signed by Isabelle Preuilh, that the addition of ethanol to a composition that falls within the preferred embodiment of Cameron results in a composition having substantially reduced viscosity and foaming capability. As Cameron clearly teaches the desirability of providing foam stabilizers to give a foaming composition (see column 2, lines 40-55, in particular), it is considered

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that one of ordinary skill in the art would not have found it obvious, based on the teachings of Cameron, to provide an ingredient that appears to significantly reduce the foaming capabilities and viscosity of the composition.

However, claim 67 is being newly rejected for the reasons as discussed below.

Applicants arguments regarding the rejections of claims 31-32, 37-42, 44, 46, 52-66 over the prior art of record have been considered but have not been found persuasive.

The reasons for the rejections of the claims are as follows.

Claim Objections

Claims 46 is objected to for depending from canceled claim 45. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for having a lack of antecedent basis for the phrase "the corticoid" as recited in the claim. Claim 31, from which claim 32 depends, recites an active principle which is clobetasol 17-propionate, but otherwise does not recite corticoids. Accordingly, as it is not clear which corticoid is being referred to in the claim, claim 32 is rejected as being indefinite under 35 U.S.C. 112, second paragraph.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for having a lack of antecedent basis for the phrase "said amount" as recited in the claim. Claim 45, from which claim 46 depends, has been canceled, and thus the "amount" being referred cannot be determined. Accordingly, as the metes and bounds of the claim cannot be determined, claim 45 is indefinite under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 37-42, 44, 46 and 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,722,837 to William W. Cameron, issued

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February 2, 1988 in view of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology (of record), and further in view of U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999.

Cameron teaches a medicated shampoo composition comprising 0.1-0.5% hydrocortisone, 20-35% detergent, 1-6% thickener, preservative and other ingredients, wherein the detergent can be combination of sodium lauryl sulfate (anionic surfactant) and cocoamidopropyl betaine (amphoteric surfactant.) Cameron further teaches that the medicated shampoo is suitable for the treatment of scalp disorders such as flaking, scaling, dandruff, seborrhea, eczema, psoriasis and others (see abstract and column 1, line 5 through column 6, line 35, in particular.) Cameron does not specifically teach the claimed propenetrating agents or the combination of anionic and amphoteric surfactants as recited in the claims.

Hirota teaches a composition for the scalp that is suitable for the treatment of conditions such as dandruff and scalp itching (see abstract, in particular.) Hirota teaches that the composition comprises a polyalkylene glycol monoalkyl ether of formula (I) (see abstract, in particular), such as diethylene glycol monoethyl ether (i.e. ethoxydiglycol as recited in claim 44), and that the component shows beneficial effects when provided in a hair care composition, such as the suppression of dandruff and itching as well as controlling the growth of bacterial flora and maintaining moisture on

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the scalp (see paragraphs 0008-0009, in particular.) Hirota teaches that an amount of the polyalkylene glycol can be from 0.1 to 5% by weight (see abstract, in particular), which meets the limitation as recited in the claim. Thus, Hirota teaches that a scalp treatment formulation can comprise the recited propenetrating agent of ethoxydiglycol for the treatment of scalp disorders such as dandruff and itching.

The Handbook of Cosmetic Science and Technology teaches that amphoteric surfactants provide foam stabilization in combination with the ability to mitigate irritancy of other materials, such as primary surfactants and, in some cases, will modify product viscosity. They are taught as being compatible with anionic surfactants, wherein anionic surfactants are taught as the primary surfactants. See pages 220-224, in particular.

Accordingly it would have been obvious to one of ordinary skill in the art to provide the ethoxydiglycol of Hirota to the scalp treatment composition of Cameron, because Cameron teaches treating scalp conditions such as dandruff and other conditions associated with itching, such as psoriasis, and Hirota teaches that ethoxydiglycol provides benefits in the treatment of dandruff and itching. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ethoxydiglycol of Hirota in the composition of Cameron with the expectation of forming a scalp treatment composition suitable for the treatment of scalp disorders such as dandruff and psoriasis.

It would furthermore have been obvious to one of ordinary skill in the art at the time the invention was made to provide the composition of Cameron and comprising both the anionic and amphoteric surfactants as claimed because of the expectation of achieving a composition that is more stable and that decreases irritation, as taught by the Handbook of Cosmetic Science and Technology.

Cameron, Hirota and the Handbook do not specifically teach providing the specific active principle that is clobetasol 17-propionate in the scalp treatment composition, as recited in claim 31.

Kligman teaches methods of treating inflammatory dermatosis (see abstract, in particular.) Disclosed are compositions comprising a combination of clobetasol propionate or triamcinolone acetonide or hydrocortisone and tretinoin, wherein the corticosteroid comprises 0.00001-3% of the composition. It is disclosed that these compounds work synergistically. The compositions are disclosed as taking on various forms, such as creams, dressings, gels, lotions, ointments or liquids. Further examples of suitable retinoids disclosed include retinyl palmitate and retinyl propionate. The retinoids can be natural or synthetic (see column 1, line 19 through column 12, line 20, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the compounds taught by Kligman into the

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composition of the combined references because of the expectation of success in achieving a composition that exhibits a synergistic effect in treating chronic dermatosis, such as seborrheic dermatitis, atopic dermatitis, contact dermatitis, psoriasis, and others, and because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Accordingly, claims 31-32, 37-42, 44, 46 and 57-61 are obvious over the teachings of the references.

Furthermore, regarding the specific amount of the anionic and amphoteric surfactants provided, as recited in claims 31 and 64-65, it is noted that Cameron teaches that an amount of a detergent provided can be from 25-35% (see column 2, lines 55-70, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of anionic and/or amphoteric surfactant provided in the composition, according to the guidance provided by Cameron, Hirota, the Handbook of Cosmetic science and Technology and Kligman, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

While the ratio of anionic to amphoteric surfactant, for example as recited in claim 66, is not specifically taught, the specific amount of a propenetrating agent that is a glycol ether, as recited in claim 31, and the ratio of anionic surfactant to propenetrating agent as recited in claim 31 are also not specifically taught, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Accordingly, claims 31 and 66 are obvious over the references.

The Examiner respectfully points out that the recitation “foaming” and “for washing and treating the hair and/or scalp” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Regarding claims 61-63, Cameron, Hirato, the Handbook and Kligman teach the composition is suitable for treatment of conditions such as dandruff and psoriasis, as

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discussed above, and thus render obvious methods of applying the compositions to the scalp for such treatment.

Claim 55 is rejected under 35 U.S.C. 103(a) above as being unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology and U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999, as applied to claims 31, 32, 37-42, 44, 46, 51 and 57-66 above, and further in view of U.S. Patent No. 5,378,731 to Andrews et al, issued January 3, 1995.

Cameron, Hirota, the Handbook of Cosmetic Science and Technology and Kligman are applied as discussed for claims 31, 32, 37-42, 44, 46, 51 and 57-66 above, and teach the hair and/or scalp treatment composition as recited in the claims.

The references do not specifically teach that a pH of the composition is between 2 and 9, as recited in claim 55.

Andrews et al. teaches a medicated shampoo for disinfecting, cleansing, conditioning and moisturizing the hair (see abstract, in particular.) Andrews et al. exemplifies such medicated shampoos having a pH of from 3.6 to 3.8 (see column 11, lines 9-44, in particular), which meets the range limitation of claim 55.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the treatment shampoo of Cameron, Hirota, the Handbook and Kligman with a pH of 3.6-3.8, as taught by Andrews et al, with the expectation of achieving a cosmetically acceptable formulation that is safe for application to the hair and scalp.

Claims 52-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology and No. U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999, as applied to claims 31, 32, 37-42, 44, 46, 51 and 57-66 above, and further in view of U.S. Patent No. 5,661,118 to Cauwet et al, issued August 26, 1997.

Cameron, Hirato, The Handbook of Cosmetic Science and Technology and Kligman are applied as discussed for claims 31, 32, 37-42, 44, 46, 51 and 57-66 above, and teach the claimed composition for the treatment of the hair and/or scalp. The references do not teach the specific cationic polymers and ceramides as recited in claims 52-54 and 56.

Cauwet et al. teaches hair and skin washing and treatment compositions based on ceramide and/or glycosphingolipid and cationic polymers. The combination of cationic polymer and ceramide and/or glycosphingolipid provides synergistic detangling. Cationic polysaccharides are taught as cationic polymers. Disclosed is a composition comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guard hydroxypropyltrimmonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. Cationic polymers comprise 0.05-5% of the composition (see column 13, line 1 through column 20, line 65, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the cationic polymers, ceramides and glycosphingolipids of Cauwet et al. in the shampoo composition of Cameron, Hirota, the Handbook and Kligman because Cameron, Hirota, the Handbook and Kligman teach a shampoo composition for the treatment of scalp conditions, and Cauwet et al. teaches cationic polymers and ceramides and glycosphingolipids that are advantageously added to shampoo compositions for detangling. Thus, one of ordinary skill in the art would have been motivated to include the cationic polymers, ceramides and glycosphingolipids with the expectation of providing a suitable additive for the shampoo composition.

Claims 31-32, 37-42, 44, 46, 55 and 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999, in view of U.S. Patent No. 4,329,334 to Su et al, issued May 11, 1982.

Kligman teaches that corticosteroids are the most widely prescribed drugs to treat dermatologic disease, such as seborrheic dermatitis (i.e. dandruff) (see column 1, lines 5-35, in particular.) Kligman teaches that the effective corticosteroids include clobetasol propionate (i.e. clobetasol 17-propionate) (see Table I, in particular.) Kligman teaches that the carrier provided for such corticosteroids can take a wide variety of physical forms (see column 7, lines 15-34, in particular), and that a suitable dosage of the corticosteroid in the composition can be from 0.0001 to 3 weight percent (see column 7, lines 33-38, in particular), such as 0.05% clobetasol propionate (see column 7, lines 40-52, in particular), which is an amount that meets and/or overlaps with that claimed.

Kligman does not specifically teach that the corticosteroid is provided in the form of a foaming composition for washing and treating the hair and/or scalp, comprising an anionic surfactant, an amphoteric surfactant, and a propenetrating agent, as recited in claim 31.

Su et al. teaches an aqueous anionic-amphoteric based shampoo for the treatment of scalp conditions such as dandruff (see abstract and column 1, lines 15-25, in particular.) Su et al. teaches that the composition is beneficial because it provides treatment of dandruff via an antimicrobial active, while also having anionic and amphoteric surfactants that cleanse and condition hair in a single operation (see column 1, lines 5-15, in particular.)

Su et al. teaches that the shampoo compositions must contain surfactants, usually based on anionic surfactants, but which can also comprise amphoteric-anionic surfactant mixtures, among others (see column 1, line 55 through column 2, line 23, in particular.) Su et al. teaches that the shampoo can comprise 0.1-7.5% of an amphoteric surfactant and 10-40% of an anionic sulfate or sulfonate surfactant (see abstract, in particular), which are amounts that meet and or overlap with those recited in the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each surfactant provided in the composition, according to the guidance provided by Su et al, to provide a composition having desired properties, such as desired cleaning properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Thus, Su et al. teaches a shampoo comprising anionic and amphoteric surfactants for the treatment of dandruff

Su et al. furthermore teaches that the composition can comprise from 0.5-2% by weight of a lower aliphatic monohydric or polyhydric alcohol (see abstract, in particular), to enhance the cleansing action of the shampoo (see column 6, lines 42-50, in particular.) Su et al. teaches that the alcohol used therein may be ethyl alcohol, propyl alcohol, or isopropyl alcohol, among others (see column 6, lines 40-55, in particular), and thus teaches providing the propenetrating C1-C4 volatile alcohols, as recited in claim 31.

Su et al. does not specifically teach providing the recited amount of the propenetrating agent, or the ratio of anionic surfactant to propenetrating agent that is between 0.1 to 10, as recited in claim 31. However, it is noted that Su et al. teaches providing amounts of each component that are close to those as claimed. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the anionic and propenetrating agent provided in the composition, and thus optimize the ratio therebetween, according to the guidance provided by Su et al, to provide a composition having desired properties, such as desired cleansing and washing properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Thus, Su et al. renders obvious an aqueous shampoo composition for the treatment of dandruff having the anionic surfactant, amphoteric surfactant and propenetrating agent as claimed.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the clobetasol propionate of Kligman via the shampoo vehicle of Su et al, because Kligman teaches the corticosteroid can be topically applied for the treatment of dandruff, and can be applied via a variety of different vehicles, and Su et al. teaches that a shampoo formulation can be used to simultaneously deliver an active agent while also providing cleansing and conditioning of hair. Thus, one of ordinary skill in the art would have been motivated to provide the clobetasol propionate via the shampoo vehicle, with the expectation of providing a composition suitable for treating dandruff while imparting added cleansing and conditioning benefits. Accordingly, claim 31 is obvious over the teachings of Kligman and Su et al.

It is respectfully pointed out that the recitation that the composition is a "foaming" composition as in claim 31 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.) It is furthermore noted that Su et al. teaches that the composition has desirable foaming, lathering, deterative and conditioning properties (see

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column 6, lines 55-65, in particular), and thus the shampoo of Su et al. is considered to be a "foaming composition" as recited in claim 31.

Regarding claim 32, Kligman teaches providing clobetasol propionate, as discussed above.

Regarding claims 37-39, Su et al. teaches that the anionic surfactant can be sodium lauryl sulfate, among others (see column 4, lines 45-68, in particular), and thus teaches the anionic surfactants as recited in the claims. Regarding claims 40-42, Su et al. teaches that the amphoteric surfactant can be betaines, sulfobetaines, and others, such as cocobetaines, cocoylbetaines and cocoamidobetaines (see column 5, lines 15-55, in particular.)

Regarding claim 44, Su et al. teaches providing ethanol and isopropanol as cleansing agents, as discussed above. Regarding claim 46, Kligman teaches that an amount of the corticosteroid provided can be from 0.0001 to 3 weight percent (see column 7, lines 33-38, in particular), such as 0.05% clobetasol propionate (see column 7, lines 40-52, in particular), which is an amount that meets and/or overlaps with that claimed. Regarding claim 55, Su et al. teaches that a pH of the composition may be from 6.5 to 7.5 (see column 6, lines 1-20, in particular), which meets the limitation of the range as claimed. Regarding claims 57-58 Su et al. teaches that the composition can contain viscosity modifiers and thickening agents (see column 7, lines 10-15 and 30-35,

in particular), as well as pearlescing agents, perfumes, coloring agents, and others (see column 7, lines 1-15, in particular.)

Regarding claim 59, Su et al. teaches the composition is aqueous (see abstract, in particular), and thus teaches the composition is in liquid form. Regarding claim 60-61, Su et al. and Kligman both teach the composition for the treatment of dandruff, and thus teach a medicament composition and a method of application of the composition to the scalp, as recited in the claims.

Regarding claims 62-63, it is noted that Kligman also teaches that corticosteroids such as clobetasol propionate are suitable for the treatment of various dermatoses, including psoriasis (see column 1, line 30 through column 2, line 5, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the composition of Kligman and Su et al. for the topical treatment of psoriasis on the scalp, with the expectation of achieving treatment of the condition.

Regarding claims 64-66, Su et al. teaches the shampoo composition can contain 10-40% by weight of the anionic sulfate or sulfonate surfactant, and 0.1-7.5% by weight of amphoteric surfactant (see abstract, in particular), which are amounts that meet and/or overlap with those recited in claims 64-65. Su et al. also exemplifies compositions having a ratio of the anionic to amphoteric surfactant that meet the range

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limitation as recited in claim 66 (see Examples 1-2, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of anionic and/or amphoteric surfactants provided in the composition, and thereby vary and/or optimize the ratio of such surfactants, according to the guidance provided by Kligman and Su et al, to provide a composition having desired properties, such as desired cleansing and foaming properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 52-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999, in view of U.S. Patent No. 4,329,334 to Su et al, issued May 11, 1982, as applied to claims 31-32, 37-42, 44, 46, 55 and 57-66 above, and further in view of U.S. Patent No. 5,661,118 to Cauwet et al, issued August 26, 1997.

Kligman and Su et al. are applied as discussed above, and teach the claimed composition for the treatment of the hair and/or scalp. The references do not teach the specific cationic polymers and ceramides as recited in claims 52-54 and 56.

Cauwet et al. teaches hair and skin washing and treatment compositions based on ceramide and/or glycosphingolipid and cationic polymers. The combination of cationic polymer and ceramide and/or glycosphingolipid provides synergistic detangling. Cationic polysaccharides are taught as cationic polymers. Disclosed is a composition comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guard hydroxypropyltrimmonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. Cationic polymers comprise 0.05-5% of the composition (see column 13, line 1 through column 20, line 65, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the cationic polymers, ceramides and glycosphingolipids of Cauwet et al. in the shampoo composition of Kligman and Su et al, because Kligman and Su et al. teach a shampoo composition for the treatment of scalp conditions, and Cauwet et al. teaches cationic polymers and ceramides and glycosphingolipids that are advantageously added to shampoo compositions for detangling. Thus, one of ordinary skill in the art would have been motivated to include the cationic polymers, ceramides and glycosphingolipids with the expectation of providing a suitable additive for the shampoo composition.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999, in view of U.S.

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Patent No. 4,329,334 to Su et al, issued May 11, 1982, as applied to claims 31-32, 37-42, 44, 46, 55 and 57-66 above, in view of U.S. Patent No. 4,722,837 to William W. Cameron, issued February 2, 1988, and further in view of U.S. Patent No. 5,661,118 to Cauwet et al, issued August 26, 1997 and U.S. Patent No. 5,631,003 to Mueller et al, issued May 20, 1997.

Kligman and Su et al. are applied as discussed above, and render obvious an aqueous shampoo composition containing clobetasol propionate, an amphoteric surfactant such as a cocoyl betaine, an anionic surfactant such as an anionic alkyl sulfate, and an alcohol. Su et al. teaches that the composition can contain 65-80% water (see column 4, lines 1-8, in particular), from 0.1-7.5% of the amphoteric surfactant (see abstract, in particular), and can contain an alcohol that is ethanol to improve cleansing in an amount of from 0.5-2% by weight (see abstract, in particular.) Kligman teaches that the clobetasol propionate can be provided in an amount of 0.05% (see column 7, lines 40-50, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of clobetasol propionate, ethanol, amphoteric surfactant and water provided in the composition, according to the guidance provided by Kligman and Su et al, to provide a composition having desired properties, such as desired cleansing and treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Kligman and Su et al. do not teach providing the specific anionic surfactant that is sodium lauryl ether sulphate, as recited in claim 67. However, Su et al. does teach that the anionic surfactant can be an anionic sulfate (see column 4, lines 35-68, in particular.)

Cameron teaches a medicated shampoo composition (see abstract, in particular.) Cameron teaches that such shampoo compositions can contain detergents such as sodium lauryl sulfate and sodium laureth sulfate (sodium lauryl ether sulphate), (see column 2, lines 22-35, in particular), and thus teaches providing the anionic surfactant as recited in claim 42 in a shampoo composition.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the sodium laureth sulfate surfactant of Cameron in the shampoo composition of Kligman and Su et al, because Kligman and Su et al. teach that the composition can contain anionic surfactants that are anionic alkyl sulfates, and Cameron teaches that anionic sulfates suitable for use as surfactants (detergents) in shampoo compositions include sodium laureth sulfate. Thus, one of ordinary skill in the art would have been motivated to provide the sodium laureth

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sulfate in the shampoo composition of Kligman and Su et al, with the expectation of providing a suitable anionic surfactant for the composition.

Regarding the amounts of the anionic surfactant provided in the composition, it is noted that Su et al. teaches that the anionic sulfate can be provided in an amount of from 10-40% by weight, which is an amount that overlaps with that claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the anionic surfactant provided in the composition, according to the guidance provided by Kligman, Su et al. and Cameron, to provide a composition having desired properties, such as desired cleansing and foaming properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Kligman, Su et al. and Cameron do not specifically teach providing polyquaternium-10 in the shampoo composition, as recited in claim 67.

Cauwet et al. teaches a hair washing composition (shampoo) comprising surface active agents and polymers containing cationic groups, to give a conditioning effect to hair (see abstract and column 1, lines 12-20, in particular.) Cauwet et al. teaches that

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cellulosic polymers such as polyquaternium-10 can be advantageously provided in such hair washing compositions (see column 3, lines 40-70 and Example 14, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the polyquaternium-10 of Cauwet et al. in the shampoo composition of Kligman, Su et al. and Cameron, and because Kligman, Su et al. and Cameron teach a shampoo composition for the treatment of scalp conditions, and Cauwet et al. teaches that polyquaternium 10 is a cationic polymer that is advantageously added to shampoo compositions. Thus, one of ordinary skill in the art would have been motivated to include the polyquaternium-10 with the expectation of providing a suitable additive for the shampoo composition.

Regarding the amount of polyquaternium-10 provided in the composition, it is noted that Cauwet teaches that polymers such as polyquaternium-10 can be provided in an amount of from 0.05-5% by weight (see column 13, lines 1-10, in particular), and thus teaches providing an amount that overlaps with that claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of polyquaternium-10 provided in the composition, according to the guidance provided by Kligman, Su et al, Cameron and Cauwet et al, to provide a composition having desired properties, such as desired conditioning properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Kligman, Su et al, Cameron and Cauwet et al. do not specifically teach providing citric acid and sodium citrate in the composition, as recited in the claim. However, Cameron does teach that medicated shampoo compositions for dermatological treatment can comprise pH adjusters (see column 2, lines 33-37, in particular)

Mueller et al. teaches that typical constituents of hair treatment preparations include pH regulators, such as a citric acid/sodium citrate buffer (see column 6, lines 35-40 and line 65, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the citric acid/sodium citrate buffer of Mueller et al. in the medicated shampoo/scalp treatment composition Kligman, Su et al, Cameron and Cauwet et al, because the references teach that it is known to provide pH adjusters, and Mueller et al. teaches that citric acid/sodium citrate buffers are typical constituents of hair care treatment products. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the citric acid/sodium citrate buffer of Mueller et al. in the composition of Kligman, Su et al, Cameron and Cauwet et al, with the expectation of providing a pH adjustor suitable for a shampoo/scalp treatment composition.

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Accordingly, a composition that consists of the ingredients as recited in claim 67 is considered to be obvious over the teachings of the prior art.

Regarding the specific amounts of the citric acid and sodium citrate as recited in the claim, it is noted that it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ingredients provided in the composition, according to the guidance provided by Kligman, Su et al, Cameron, Cauwet et al. and Mueller, to provide a composition having desired properties, such as a desired pH. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Response to Arguments

Applicant's arguments regarding the rejections of the claims have been fully considered but they are not persuasive.

In particular, Applicants argue that Hirota does not teach providing propenetrating agents to suit the purposes of the particular nature of the invention, and also argues that Hirota teaches providing an amount of the ethanol and polyalkylene glycol monoalkyl ethers that would greatly exceed the amount claimed, and thus that it would not be

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obvious to incorporate the agents of Hirota into the composition of Cameron to achieve the composition as claimed.

The Examiner respectfully disagrees. The Examiner notes that Hirota teaches compositions for the scalp that is suitable for the treatment of conditions such as dandruff and scalp itching comprising a polyalkylene glycol such as diethylene glycol monoethyl ether (i.e. ethoxydiglycol as recited in claim 44), and that the component shows beneficial effects when provided in a hair care composition, such as the suppression of dandruff and itching as well as controlling the growth of bacterial flora and maintaining moisture on the scalp (see paragraphs 0008-0009, in particular.) Hirota also teaches that an amount of the polyalkylene glycol can be from 0.1 to 5% by weight (see abstract, in particular), which meets the limitation as recited in the claim. Accordingly, it is considered that it would have been obvious to one of ordinary skill in the art to provide the ethoxydiglycol of Hirota in the amount as taught by Hirota in the scalp treatment composition of Cameron, because Cameron teaches treating scalp conditions such as dandruff and other conditions associated with itching, such as psoriasis, and Hirota teaches that ethoxydiglycol provides benefits in the treatment of dandruff and itching. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ethoxydiglycol of Hirota in the composition of Cameron with the expectation of forming a scalp treatment composition suitable for the treatment of scalp disorders such as dandruff and psoriasis.

Applicants' further seek to overcome the prima facie case of obviousness over Cameron in view of Hirota and the Handbook, by presenting testing results via a declaration submitted under 37 C.F.R. 1.132 on February 26, 2007, and signed by Isabelle Preuilh. The declaration shows results for a particular composition that falls within the scope of the claims (Clobex shampoo) and have 10% ethanol as the propenetrating agent, as compared to: a composition having the same ingredients as the Clobex shampoo but being absent the clobetasol propionate active agent (Composition A); a composition having the same ingredients as the Clobex shampoo but being absent the active agent and ethanol (Composition B); a composition that falls within the range of that exemplified in Example I of Cameron et al, and being absent ethanol (Composition C); and a composition that falls within the range of Example I of Cameron, but with 10% by weight of added ethanol (water qsp) (Composition D.) The viscosities and foaming power of each composition were measured and compared.

The results show that while the ethanol-containing Clobex shampoo and ethanol-containing Clobex-type Composition A had similar viscosities and foaming power as the non-ethanol containing Clobex-type Composition B, the incorporation of ethanol into the exemplified composition of Cameron (Composition C) yielded a composition having substantially reduced viscosity and foaming power (Composition D.) Thus, Applicants assert that while the incorporation of ethanol into prior art compositions such as that of Cameron "breaks" such compositions by significantly reducing the foaming power and viscosity of such compositions, the incorporation of ethanol into the particular

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composition as claimed provides unexpected results in that the compositions surprisingly do not exhibit a substantial decrease in viscosity or foaming power.

While the Examiner finds these results persuasive to withdrawn the rejection over Cameron in view of Hirota of the specific composition recited in claim 67, which corresponds to the Clobex shampoo composition evaluated in the declaration, as such composition appears to show "unexpected results" in terms of viscosity and foaming power over the preferred embodiment of Cameron having ethanol added thereto, the Examiner does not find the evidence persuasive to overcome the rejections of the claims drawn to compositions having broader scope. The Examiner notes that evidence of unexpected results is required to be reasonably commensurate in scope with the claimed invention. See, e.g., *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). Applicants have shown results for the particular composition that corresponds to claim 67, having particular surfactants, cationic polymer, propenetrating agents, etc, in the particular amounts as claimed. Applicants have not shown that such results are also achieved for all compositions containing any of the claimed propenetrating agents, including ethoxydiglycol, or other alcohols, any amphoteric or anionic surfactants corresponding to those claimed, and in any amounts meeting the limitations for example of claim 31.

It is noted that evidence of unexpected results requires a nexus between the results as presented and the features being claimed. In the instant case, while the results show that an improved formulation can be achieved for a specific composition content, it is not clear what aspect of the formulation allows for the improved viscosity/foaming power results. Applicants have claimed a composition having ranges of weight percentages of the components and even a ratio of anionic surfactant to propenetrating agent (e.g. claim 31), but have not given any results to demonstrate how these various factors (amount and type of propenetrating agent, amount and type of surfactants, ratios, etc) might contribute to the desirable results. As such, the desirable results demonstrated by the specific composition tested by Applicants cannot reasonably be extrapolated to the broader set of compositions having the ingredients/weight percentages, ratios, etc, as recited for example in claim 31. Accordingly, Applicants evidence of unexpected results is not sufficient to overcome the prima facie case of obviousness over Cameron in view of Hirota and the Handbook for the broader composition claims

It is furthermore noted that evidence of unexpected results must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). The Examiner notes that Applicants have not compared to the Kligman and Su et al. references that are being applied in the instant action. Accordingly, Applicants do not

provide sufficient evidence of unexpected results in comparison to the closest prior art.
See MPEP 716.02(e).

Conclusion

No claims are allowed.

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is listed in the accompanying PTO-892 form.

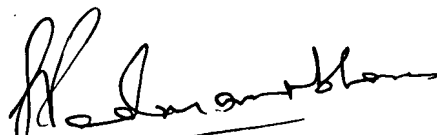
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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